

REMARKS

Applicants acknowledge receipt of the Office Action^{*} mailed June 24, 2009.

In the Office Action, the Examiner rejected claims 3-5 under 35 U.S.C. § 112, second paragraph; rejected claims 1, 8, 10-13, 16, and 36 under 35 U.S.C. § 102(b) as being anticipated by *Tseung* (U.S. Patent No. 5,439,649); rejected claims 2, 6-7, 17-19, 21-23, 25-30, and 32-34 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung* in view of *Ganz* (WO 02/064812); rejected claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung* in view of *Rhett* (U.S. Patent No. 5,839,091); rejected claims 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung*; and rejected claims 9 and 35 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung* in view of *Bernstein* (U.S. Patent No. 5,696,887).

By this Amendment, Applicants amend claims 1, 3-12, 17, 21-23, 25, 27-30, and 34-36, and cancel claims 13 and 26, without prejudice or disclaimer. Claims 1-12, 14-19, 21-23, 25, 27-30, and 32-36 remain pending. Of these claims, claims 1, 6-10, 17, 21, 25, 30, 35, and 36 are independent.

Applicants traverse the rejections above and respectfully request reconsideration for at least the reasons that follow.

^{*} Applicants submit that although the Examiner has indicated in Box 2a of the PTOL-326 that, "[t]his action is **FINAL**," the Office Action does not include a statement of finality at the end of the "Detailed Action" section of the Office Action. In addition, according to the PAIR system, this Office Action has been designated as a "Non-Final Office Action." Accordingly, Applicants are also treating this Office Action as a Non-Final Office Action. Applicants request that the Examiner address this issue in the next communication.

I. 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTION

Claims 3-5 stand rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner asserts, "[c]laims 3-5 all recite the limitation 'said sample'. There is insufficient antecedent basis for this limitation in the claim . . ." (*Office Action*, p. 2, para. 5). Applicants submit that the rejection of claims 3-5 has been rendered moot by the amendments to those claims. Applicants therefore request that the rejection of claims 3-5 under 35 U.S.C. § 112, second paragraph, be withdrawn.

II. 35 U.S.C. § 102(b) REJECTION

Claims 1, 8, 10-13, 16, and 36 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Tseung*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that the claims are patentably distinguishable over *Tseung* at least for the reasons set forth below. Applicants further submit that the rejection of claim 13 has been rendered moot by its cancellation

In order to properly establish that *Tseung* anticipates Applicants' claimed invention under 35 U.S.C. § 102, each and every element of each of the claims must be disclosed, either expressly or under principles of inherency, in that single reference. Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

With respect to independent claim 1, and similarly independent claims 10 and 36, *Tseung* fails to teach or suggest, at least, an automatic staining apparatus: "wherein the robotic element comprises an optical sensor configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process; and a

control element to which the robotic element is responsive, the control element configured to monitor insertion or removal of the at least one removable reagent container during the staining process."

Optical Sensor

The Examiner asserts that, "TSEUNG teaches an automatic staining apparatus comprising . . . an image capture 2D optical sensor configured to two dimensionally image at least one element in said automatic staining apparatus (Column 16, lines 42-51)." (*Office Action*, p. 3, ll. 6-8). The passage cited by the Examiner merely discloses that the automated staining apparatus may optically scan slides in a microscopic slide tray or other container for microscope slides so that a human operator does not need to enter information into the computer. Such passage, however, does not disclose that the optical sensor can automatically identify new slides and reagent bottles loaded into the apparatus during the staining process.

Control Element

The Examiner asserts that, "TSEUNG teaches an automatic staining apparatus comprising . . . a control element to which said robotic element is responsive (Column 5, lines 7-13) . . . , wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51)." (*Office Action*, p. 3, ll. 1-11). Applicants respectfully disagree.

The Examiner first relies on column 5, lines 7-13 of *Tseung* for support of the "control element" limitation recited in independent claims 1, 10, and 36 above. The passage discloses that

standardized motions of the arm can be programmed into the control unit so that individual microscope slides at specific fixed locations in the microscope slide holder can be treated with reagents and/or wash fluids obtained from reagent containers or from liquids supplied through the hollow tip head on the movable arm.

The control unit controls motions of the moveable arm 30 for treating the microscope slides with reagents and/or wash fluids obtained from reagent containers 110. The control unit, however, does not monitor insertion or removal of at least one removable reagent container during the staining process.

The Examiner then relies on column 4, lines 10-14 of *Tseung* for further support of the "control element" limitation. The passage discloses that

[m]otors or other means for moving the arm are provided under the control of a computer or other electronic control device that allows programming of movement of the arm between various work locations on or within the framework.

The computer or the electronic control device controls movement of the arm. The computer or the electronic control device, however, does not monitor insertion or removal of at least one removable reagent container during the staining process. The Examiner also relies on column 16, lines 42-51 of *Tseung* for support of the "control element" limitation above. This passage discloses that

[o]ther optional features that can be included on the apparatus include devices intended to . . . optically scan slides in a microscope slide tray or other container for microscope slides . . . Such information could be provided . . . by a standard bar code attached to an individual microscope slide or other component. Multiple reagent containers can be provided so that different staining operations can be carded out under the control of the bar code and the computer and its pre-program software.

The computer and its pre-program software merely controls different staining operations using bar codes. The computer and its pre-program software, however, do not monitor insertion or removal of the at least one removable reagent container during the staining process.

With respect to independent claim 8, *Tseung*, fails to teach or suggest, at least, an automatic staining apparatus comprising: "an optical sensor configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process and locate pre-selected reference features for self-calibration of the robotic element; and a control element to which the robotic element is responsive, the control element configured to monitor insertion or removal of the at least one reagent container during the staining process."

The Examiner asserts that, "TSEUNG teaches an automatic staining apparatus comprising . . . an optical sensor adapted to locate pre-selected reference features for self-calibration of the robotic element (Column 16, lines 42-51)." (*Office Action*, p. 3, ll. 12-19). And, as discussed above, with respect to the "control element" limitation, the Examiner relies on column 5, lines 7-13, column 4, lines 10-14, and column 16, lines 42-51 of *Tseung*. Applicants respectfully disagree.

As discussed above, column 16 of *Tseung* merely discloses that the automated staining apparatus may optically scan slides in a microscopic slide tray or other container for microscope slides so that a human operator does not need to enter information into the computer. Such passage, however, does not disclose that the optical sensor can locate pre-selected reference features for self-calibration of a robotic

element. Additionally, *Tseung* fails to disclose the “control element” limitation also for the reasons discussed above.

Tseung therefore fails to disclose each and every element of the claims, either expressly or inherently. See M.P.E.P. § 2131. Accordingly, independent claims 1, 8, 10, and 36, and claims 11, 12, and 16 which depend from claim 10, are patentable over *Tseung*. Applicants therefore request that the rejection of claims 1, 8, 10-13, 16, and 36 under 35 U.S.C. § 102(b) be withdrawn.

III. 35 U.S.C. § 103(a) REJECTIONS

Applicants traverse the rejection of claims 2, 6-7, 17-19, 21-23, 25-30, and 32-34 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung* in view of *Ganz*. Applicants respectfully disagree with the Examiner’s arguments and conclusions and submit that independent claims 6, 7, 17, 21, 25, and 30 patentably distinguish over *Tseung* and *Ganz* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See *id.* “Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.” M.P.E.P. § 2141(III).

With respect to independent claim 6, the Examiner admits that “TSEUNG . . . does not explicitly disclose recording image data, robotic calibration points, and feeding the data to a control element.” (*Office Action*, p. 6, ll. 21-23).

Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches a camera that images the slides and software that analyzes the identification, positioning . . . and alignment information . . . provided by the camera and stores it . . ." (*Id.* at p. 6, line 23 - p. 7, line 3). Applicants respectfully disagree.

Ganz appears to read the bar code and inspect the positioning and alignment of the slide 4A1 on a locating plate 3A. The software then analyzes the position data and stores the information. The information stored is later used to adjust the positions of the slide 4A1 and a dispense head 6 to ensure accurate placement of solution on the slide 4A1. (*Ganz*, p. 5, line 29 - p. 6, line 4). *Ganz*, however, fails to teach or suggest a method of recording calibration reference points of the apparatus, *i.e.*, it only monitors the position of the slide.

Ganz also fails to teach or suggest a control element to which a robotic element is responsive, the control element configured to monitor insertion or removal of at least one reagent container during a staining process. *Ganz* focuses only on the position of the slide.

With respect to independent claim 7, the Examiner admits that "TSEUNG . . . does not explicitly disclose the optical sensor responsive to the robotic element." (*Office Action*, p. 7, ll. 11-13).

Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches the camera (optical sensor) images the slide after the linear actuator (robotic element) moves the slide under the dispense head . . ." (*Id.* at p. 7, ll. 14-15). Applicants respectfully disagree.

Ganz fails to teach an optical sensor configured to automatically identify new slides and reagent bottles loaded into the automatic staining apparatus during the staining process. The camera 12 disclosed in *Ganz*, which the Examiner equates to the claimed "optical sensor," is a self-contained camera with image processing capabilities. The camera 12 can snap pictures while in dynamic motion, process the image for results, pass the results off to the PC control system, and prepare for the next image acquisition. (*Ganz*, p. 14, ll. 6-10). The camera 12, however, does not automatically identify new slides and reagent bottles loaded into an automatic staining apparatus during a staining process.

Furthermore, *Ganz* fails to teach or suggest recording calibration reference positions for slide racks. Again, *Ganz* focuses only on the position of the slide.

With respect to independent claim 17, the Examiner admits that "TSEUNG teaches the claimed invention . . . except for a computer image biological analysis element and the optical sensor recording a first before image and a second after image." (*Office Action*, p. 8, ll. 9-11).

Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample . . . and an optical sensor (camera) that records a first image of the sample before staining and records a second image of the sample after staining." (*Id.* at p. 8, ll. 12-16).

Such teaching, even if present in *Ganz*, which Applicants do not concede, however, fails to teach or suggest, "an optical sensor configured to automatically identify

new slides and reagent bottles loaded into the apparatus during the staining process.” As discussed above, the camera 12 disclosed in *Ganz*, which the Examiner equates to the claimed “optical sensor,” is a self-contained camera with image processing capabilities. The camera 12 can snap pictures while in dynamic motion, process the image for results, pass the results off to the PC control system, and prepare for the next image acquisition. (*Ganz*, p. 14, ll. 6-10). The camera 12, however, does not automatically identify new slides and reagent bottles loaded into an automatic staining apparatus during a staining process.

Ganz also fails to teach or suggest a control element to which a robotic element is response, the control element configured to monitor insertion or removal of at least one reagent container during a staining process. *Ganz* focuses only on the position of the slide.

With respect to independent claim 21, the Examiner admits that “TSEUNG . . . does not explicitly disclose biologically analyzing image data of the sample with a computer.” (*Office Action*, p. 9, ll. 6-14).

Accordingly, the Examiner relies on *Ganz* and asserts, “GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample.” (*Id.* at p. 9, ll. 15-17).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest a method of identifying at least one property in an automatic staining apparatus comprising the steps of: “feeding said image data to a control element to which said

robotic element is responsive, the control element configured to monitor insertion or removal of the at least one reagent container during the staining process," as recited in independent claim 21. Again, *Ganz* focuses only on the position of the slide.

With respect to independent claim 25, the Examiner admits that "TSEUNG . . . does not explicitly disclose biologically analyzing image data of the sample with a computer." (*Office Action*, p. 10, ll. 4-13).

Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample." (*Id.* at p. 10, ll. 13-16).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest a method of staining tissue samples in an automatic staining apparatus comprising the steps of: "feeding said image data to a control element to which said robotic element is responsive, the control element configured to monitor insertion or removal of the at least one reagent container during the staining process," as recited in independent claim 25. *Ganz* focuses only on the position of the slide.

With respect to independent claim 30, the Examiner admits that "TSEUNG . . . does not explicitly disclose a multifunction optical sensor or computer image biological analysis element." (*Office Action*, p. 11, ll. 6-8).

Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored

camera images after reagent deposition onto a slide containing a biological sample . . . and a multifunction optical sensor . . . configured to sense at least one element in said automatic staining apparatus." (*Id.* at p. 11, ll. 8-13).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest an automatic staining apparatus comprising: "a multifunctional optical sensor configured to automatically identify new slides and reagent bottles loaded into the apparatus during the staining process." As discussed above, the camera 12 disclosed in *Ganz*, which the Examiner equates to the claimed "optical sensor," is a self-contained camera with image processing capabilities. The camera 12 can snap pictures while in dynamic motion, process the image for results, pass the results off to the PC control system, and prepare for the next image acquisition. (*Ganz*, p. 14, ll. 6-10). The camera 12, however, does not automatically identify new slides and reagent bottles loaded into an automatic staining apparatus during a staining process.

As explained above, the elements of independent claims 6, 7, 17, 21, 25, and 30 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claims 6, 7, 17, 21, 25, and 30. Claims 6, 7, 17, 21, 25, and 30, and claims 2, 18, 19, 22, 23, 26-29, and 32-34 which correspondingly depend therefrom, are patentable over *Tseung* and *Ganz*. Applicants

therefore request that the rejection of claims 2, 6-7, 17-19, 21-23, 25-30, and 32-34 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claims 9 and 35 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung* in view of *Bernstein*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claims 9 and 35 patentably distinguish over *Tseung* and *Bernstein* at least for the reasons described below.

With respect to independent claim 9, the Examiner admits that "TSEUNG . . . does not explicitly disclose a first and second slide section separated by the reagent section." (*Office Action*, p. 14, ll. 10-16).

Accordingly, the Examiner relies on *Bernstein* and asserts, "BERNSTEIN teaches an apparatus for automated tissue assay in which samples are located in two sections which are separated by an element (Figure 2)." (*Id.* at p. 14, ll. 17-19). Applicants respectfully disagree.

Bernstein merely discloses that the plurality of locating holes 12, which receive the modular workstations 13, are disposed at predetermined fixed location relative to the robotic device 10. (*Bernstein*, col. 6, ll. 47-49). *Bernstein* fails to disclose at least an actual reagent section and first and second slide sections located on the bench top 11, with the first and second slide sections separated by the reagent section.

With respect to independent claim 35, the Examiner admits that "TSEUNG . . . does not explicitly disclose two staining sections separated by the reagent section." (*Office Action*, p. 15, ll. 3-14).

Accordingly, the Examiner relies on *Bernstein* and asserts, "BERNSTEIN teaches an apparatus for automated tissue assay in which samples are located in two sections which are separated by an element (Figure 2)." (*Id.* at p. 15, ll. 14-16). Applicants respectfully disagree.

As discussed above, *Bernstein* merely discloses that the plurality of locating holes 12, which receive the modular workstations 13, are disposed at predetermined fixed location relative to the robotic device 10. (*Bernstein*, col. 6, ll. 47-49). *Bernstein* fails to disclose at least an actual reagent section and at least two staining sections located on the bench top 11, with the at least two staining sections separated by the reagent section.

As explained above, the elements of independent claims 9 and 35 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claims 9 and 35. Claims 9 and 35 are patentable over *Tseung* and *Bernstein*. Applicants therefore request that the rejection of claims 9 and 35 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung* in view of *Rhett*; and the rejection of claims 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over *Tseung*. The deficiencies of *Tseung* are discussed above.

With respect to *Rhett*, the Examiner alleges "RHETT teaches an apparatus for automatic slide staining in which the optical sensor (CCD camera) is adapted to record an image of the finalized slide after said slide has been subjected to a staining protocol." (*Office Action*, p. 12, ll. 11-14). Such teaching, even if present in *Rhett*, however, does not constitute or suggest at least an automatic staining apparatus comprising at least: "a control element to which said robotic element is responsive, the control element configured to monitor insertion or removal of the at least one removable reagent container during the staining process," as recited in independent claim 1, and similarly independent claim 10.

Claims 3-5, 14, and 15 correspondingly depend from independent claims 1 and 10 and require all elements thereof. As explained above, the elements of independent claims 1 and 10 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither properly determined the scope and content of the prior art nor properly ascertained the differences between the prior art and the claims. Accordingly, no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art and a *prima facie* case of obviousness has not been established for claims 3-5, 14, and 15 at least due to their dependence. Therefore, Applicants request that the rejection of claims 3-5, 14, and 15 under 35 U.S.C. § 103(a) be withdrawn.

VI. CONCLUSION

Applicants respectfully submit that claims 1-12, 14-19, 21-23, 25, 27-30, and 32-36 are in condition for allowance.

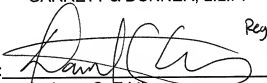
The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 
Anthony C. Tridico
Reg. No. 45,958

Reg. No. 52,639
for

Dated: November 24, 2009